RESPONSE TO REQUIREMENT FOR RESTRICTION

The Examiner required election of one of the following groups of claims:

Group I. Claims 1-22, drawn to an immunogenic composition;

Group II. Claims 23-26, drawn to a vaccine composition;

Group III. Claims 27-31, drawn to an adjuvant composition;

Group IV. Claims 32, 33, 40 and 41, drawn to a method of stimulating an immune response; and

Group V. Claims 34-36 and 40-42, drawn to a method of immunizing a host animal to induce a protective response.[1]

The Examiner also required applicants select a single species from SEQ ID NOS:1-27.

In response to the restriction requirement, applicants elect to prosecute the claims of Group I, claims 1-22 (and new claims 43-45), with traverse. In response to the species election requirement, applicants elect to proceed with SEQ ID NO:1. All claims of Group I read on this species. Should the Examiner rejoin the claims of Group II with Group I as proposed below, all elected claims will read on the elected species. It is to be understood that this election of species is for the purposes of preliminary search and examination only, and that upon allowance of a generic claim, applicants will be entitled to consideration of claims to the additional species.

Applicants expressly reserve their right under 35 USC §121 to file one or more divisional applications directed to the nonelected subject matter during the pendency of this application.

Applicants traverse this restriction requirement for the following reasons. The claims of Group I, claims 1-22 and new claims 43-45, pertain to immunogenic compositions comprising (a) an immunostimulating amount of a Neisseria antigen and (b) an immunostimulating amount of an adjuvant composition comprising an oligonucleotide

[1] Applicants note claims 37-39 were not included in any of Groups I-V. These claims are directed to methods of immunizing a host animal to induce a protective response and are therefore assumed to belong in Group V.

comprising at least one CG motif. The claims of Group II, claims 23-26, relate to a vaccine composition comprising (a) an immunostimulating amount of a Neisseria antigen and (b) an immunostimulating amount of an adjuvant composition comprising an oligonucleotide comprising at least one CG motif. As explained at page 7, lines 28-29 of the application, a vaccine is "an **immunogenic composition** which is able to induce a microbicidal immune response." (Emphasis added.) Thus, a vaccine composition is one type of an immunogenic composition, the subject matter of Group I. Accordingly, applicants submit a search of the claims of Group I and Group II together would not be overly burdensome for the Examiner.

Similarly, the claims of Group IV, claims 32, 33, 40 and 41, are directed to methods of stimulating an immune response. The claims of Group V, claims 34-36 and 40-42, are directed to methods of inducing a protective response. A protective response is a particular type of an immune response. Therefore, a search of the claims of Group IV together with the claims of Group V would not be overly burdensome. Thus, applicants propose the claims be regrouped as follows (numbering is based on the assumption that the Preliminary Amendment will be entered):

Group I, claims 1-21, 23-25 and 43-45, drawn to immunogenic and vaccine compositions;

Group II, claims 27-31, drawn to adjuvant compositions;

Group III, claims 32-39, drawn to methods of inducing immune responses.

> MPEP §803 states:
> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions. (Emphasis added.)

Applicants submit that an examination of the claims as proposed above, would not impose a serious burden on the Examiner. Indeed, applicants believe that failure to examine the claims as proposed would pose a far greater burden on the Patent and Trademark Office, by requiring a duplication of effort and resources, since a search directed to claims in Groups I and II, and

similarly Groups IV and V, would turn up overlapping art if such art existed. Accordingly, applicants respectfully traverse the above Restriction Requirement and request reconsideration thereof.

Should the Office reconsider and regroup the claims as set forth above, applicants elect to prosecute the claims of proposed Group I, claims 1-21, 23-25 and 43-45, without traverse.

PRELIMINARY AMENDMENT

Amendments to the Claims:

The following listing reflects amendments to the claims and replaces all prior versions and listings of claims in this application.

1. (Original) An immunogenic composition comprising:

(a) an immunostimulating amount of a Neisseria antigen; and

(b) an immunostimulating amount of an adjuvant composition comprising an oligonucleotide comprising at least one CG motif.

2. (Original) The composition of claim 1, wherein said Neisseria antigen is selected from the group consisting of a protein, protein-polysaccharide, protein-lipopolysaccharide, polysaccharide, and lipopolysaccharide.

3. (Currently amended) The composition of ~~any preceding~~ claim 1 or claim 2, wherein said Neisseria antigen is from *Neisseria meningitidis* or *Neisseria gonorrhoeae.*

4. (Original) The composition of claim 3 wherein said Neisseria antigen is a *Neisseria meningitidis* serogroup B peptide.

5. (Original) The composition of claim 4 wherein said peptide comprises SEQ ID NO:31.

6. (Currently amended) The composition of ~~any preceding~~ claim 1, wherein component (b) further comprises a second adjuvant.

7. (Original) The composition of claim 6, wherein said second adjuvant comprises an oil

droplet emulsion.

8. (Original) The composition of claim 7, wherein said oil droplet emulsion comprises a metabolizable oil and an emulsifying agent.

9. (Original) The composition of claim 8, wherein said oil and said emulsifying agent are present in the form of an oil-in-water emulsion having oil droplets substantially all of which are less than 1 micron in diameter and wherein said composition exists in the absence of any polyoxypropylene-polyoxyethylene block copolymer.

10. (Original) The composition of claim 9, wherein said oil is an animal oil, an unsaturated hydrocarbon, a vegetable oil, or a terpenoid.

11. (Original) The composition of claim 10 wherein said terpenoid is squalene.

12. (Original) The composition of any one of claims 8 to 11, wherein said composition comprises 0.5 to 20% by volume of said oil in an aqueous medium.

13. (Currently amended) The composition of any one of claims 8 to ~~12~~ 11, wherein said emulsifying agent comprises a non-ionic detergent or a polyoxyethylene sorbitan mono-, di-, or triester or a sorbitan mono-, di-, or triether.

14. (Currently amended) The composition of any one of claims 8 to ~~13~~ 11, wherein said composition comprises 0.01 to 0.5 % by weight of said emulsifying agent.

15. (Currently amended) The composition of ~~any preceding~~ claim 1, further comprising a separate immunostimulating agent.

16. (Original) The composition of claim 15 wherein said immunostimulating agent is

selected from the group consisting of a bacterial cell wall component and muramyl peptide.

17. (Currently amended) The composition of ~~any one of claims~~ claim 6 ~~to 17~~, wherein said second adjuvant comprises alum, incomplete Freund's adjuvant (IFA), or complete Freund's adjuvant (CFA).

18. (Currently amended) The composition of ~~any preceding~~ claim 1, wherein said oligonucleotide comprises at least one phosphorothioate bond.

19. (Currently amended) The composition of ~~any preceding~~ claim 1, wherein said oligonucleotide comprises a nucleotide sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:25, SEQ ID NO:26, and SEQ ID NO:27.

20. (Currently amended) The composition of ~~any preceding~~ claim 1, wherein said oligonucleotide comprises a CG motif flanked by two purines immediately 5' to said motif and two pyrimidines immediately 3' to said motif.

21. (Original) The composition of claim 20, wherein said oligonucleotide comprises a nucleotide sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, and SEQ ID NO:25.

22. (Cancelled)

23. (Original) A vaccine composition comprising:

a) an immunostimulating amount of a Neisseria antigen; and

b) an inummostimulating amount of an adjuvant composition comprising an oligonucleotide comprising at least one CG motif.

24. (Original) The vaccine composition of claim 23, wherein component (b) further comprises a second adjuvant.

25. (Original) The vaccine composition of claim 23 or claim 24, wherein said peptide comprises SEQ ID NO:31.

26. (Cancelled)

27. (Original) An adjuvant composition comprising:

a) an oligonucleotide comprising at least one CG motif; and

b) complete Freund's adjuvant.

28. (Original) The composition of claim 27 wherein said oligonucleotide comprises at least one phosphorothioate bond.

29. (Original) The composition of claim 27 wherein said oligonucleotide comprises a nucleotide sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:25, SEQ ID NO:26, and SEQ ID NO:27.

30. (Original) The composition of claim 27 wherein said oligonucleotide comprises a CG

motif flanked by two purines immediately 5' to said motif and two pyrimidines immediately 3' to said motif.

31. (Original) The composition of claim 30 wherein said oligonucleotide comprises a nucleotide sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, and SEQ ID NO:25.

32. (Currently amended) A method of stimulating an immune response in a host animal comprising administering to said animal a composition ~~of any one of claims~~ according to claim 1 ~~to 22~~ in an amount effective to induce an immune response.

33. (Original) The method of claim 32 wherein said host animal is a mammal.

34. (Currently amended) A method of immunizing a host animal against Neisseria infection comprising administering to said animal a composition ~~of any one of claims~~ according to claim 23 ~~to 26~~ in an amount effective to induce a protective response.

35. (Original) The method of claim 34 wherein said host animal is a mammal.

36. (Original) The method of claim 35 wherein said mammal is a human.

37. (Currently amended) A method of immunizing a host animal against Neisseria meningitidis comprising administering to said animal a composition ~~of any one of claims~~ according to claim 23 ~~to 26~~ in an amount effective to induce a protective response, wherein said antigen is a Neisseria meningitidis group B peptide.

38. (Original) The method of claim 37 wherein said peptide comprises SEQ ID NO:31.

39. (Original) The method of claim 38 wherein said host animal is a human.

40-42. (Cancelled)

43. (New) The composition of claim 12, wherein said emulsifying agent comprises a non-ionic detergent or a polyoxyethylene sorbitan mono-, di-, or triester or a sorbitan mono-, di-, or triether.

44. (New) The composition of claim 12, wherein said composition comprises 0.01 to 0.5 % by weight of said emulsifying agent.

45. (New) The composition of claim 13, wherein said composition comprises 0.01 to 0.5 % by weight of said emulsifying agent.